REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

I. Summary of the Claims

Claims 1, 11 and 17 are currently being amended. Exemplary support for this amendment can be found, *inter alia*, in paragraphs 298, 355, 368, 467, 468, 612 and the Examples, particularly Examples 20 and 33-37. No new matter is added.

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

After amending the claims as set forth above, claims 1-17, 29 and 35 are now pending in this application, of which claims 29 and 35 are withdrawn. Claims 8-10 remain pending and await examination once a generic claim is allowed.

II. Rejections under 35 U.S.C. § 112, first paragraph, enablement

A. Deposit conditions

Claims 3-7 and 13-16 were rejected for allegedly lacking enablement under 35 U.S.C. § 112, first paragraph. Specifically, the Examiner stated that with regard to ATCC Deposit No. 203055, recited in the rejected claims, "mere indication that a deposit has been made under conditions prescribed by the Budapest Treaty would not satisfy the requirement that all restrictions on access be removed on grant of the patent." Office action, page 4.

In response, Applicants have hereto provided a partially redacted copy of the ATCC deposit receipt. Applicants' representative also hereby gives the following assurance by signature below:

> Human Genome Sciences, Inc., the assignee of the present application, has deposited biological material under the terms of the Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedure with the following International Depository Authority: American Type Culture Collection ("ATCC"), 10801 University Boulevard, Manassas, Virginia 20110-2209 (present address). The deposit, referred to as DNA Plasmid HEMCZ56, was made on July 9, 1998, accepted by the ATCC, and given ATCC Accession Number 203055. In accordance with M.P.E.P. § 2410.01 and 37 C.F.R. § 1.808, assurance is hereby given that all restrictions on the availability to the public of ATCC Accession Number 203055 will be irrevocably removed upon the grant of a patent based on the instant application, except as permitted under 37 C.F.R. § 1.808(b).

Accordingly, withdrawal of the rejection is respectfully requested.

B. Method of prevention

Claims 1-7 and 11-17 were rejected under 35 U.S.C. § 112, first paragraph, for allegedly lacking enablement for preventing an inflammatory response. Specifically, the Examiner, *while acknowledging enablement for treating an inflammatory response*, asserts the specification does not support prevention of the very same responses that the claimed methods treat. Applicants respectfully traverse this rejection.

In support of this rejection, the Examiner cites Zhang (*J. Clin. Invest.* (2001) 11:1459-1468), which describes the effect of a different molecule, a truncated receptor TR6, which blocks the interaction of LIGHT/TR2 and Fas/FasL. Zhang, page 1467, first column. Zhang describes the inhibition of graft versus host disease in mouse transplants (Figure 6) as well as the inhibition of CTL development (Figure 4) and down-regulation of the production of several cytokines in stimulated cells (Figure 5). Thus, TR6 effectively inhibited several immune responses with good clinical outcome.

Applicants disagree with the Examiner's assertion that the results for TR6 shown in Zhang apply to the claimed invention, or that Zhang even shows a failure to prevent onset of an inflammatory disease. The Examiner points to the incomplete inhibition of proliferation by TR6 as support for asserting that TR6 "only inhibits, but does not prevent, in vivo and ex vivo splenic alloactivation in mice (Figure 3)." Office action, page 7. However, the

Examiner fails to explain what bearing the activity of TR6, a truncated receptor with different binding affinities, has on the present antibody-mediated methods. Zhang states that this incomplete inhibition by TR6 may very well be due to its binding of FasL and subsequent inhibition of FasL-induced apoptosis and activation-inducd T cell death. Zhang, page 1466, second column, second paragraph. Indeed, Figure 3 of Zhang shows a partial inhibition that is statistically significant compared to the controls. This inhibition combined with the significantly improved clinical outcome of Figure 6 actually supports the role of TR6 in both inhibiting and preventing the onset of disease.

The Examiner conceded that the claimed methods are enabled for treating an inflammatory response. As preventing a disease affects the same interactions, a person of skill in the art would reasonably believe that the claimed methods would also prevent the same disorders. The Examiner provides no support that the complete abolition of a response is required for prevention. Citing evidence using different molecules that affect other pathways to support speculation that not only would the present antibodies have the same effect, but that partial inhibition equates with complete lack of prevention, does not undermine the reasonable expectation that the claimed methods would prevent as well as treat the listed diseases. As long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. 112 is satisfied. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). The enablement of a method of treating an inflammatory disease reasonably correlates with the method of preventing it, and the evidence cited by the Examiner does not rebut this. Therefore, Applicants respectfully request that the rejection be withdrawn.

C. Antagonists

Claims 1-7 and 11-17 were rejected under 35 U.S.C. § 112, first paragraph, for allegedly lacking enablement for failing to recite that the antibody be neutralizing or antagonistic. Without acquiescing to this rejection and solely to advance prosecution, the claims have been amended to require that the antibody be antagonistic. Therefore, Applicants respectfully request that the rejection be withdrawn.

D. Scope of disease

Claims 1-7 and 11-17 were rejected under 35 U.S.C. § 112, first paragraph, for allegedly lacking enablement for all inflammatory diseases. Specifically, the Examiner asserts that the methods of the claimed invention only trigger certain immune pathways, but not all. Without acquiescing to this rejection and solely to advance prosecution, the claims have been amended to recite a limited number of inflammatory diseases. The Examiner has conceded that the claimed methods are at least enabled for treating inflammatory bowel disease. The full scope of the claims are enabled and request that the rejection be withdrawn.

III. Rejections under 35 U.S.C. § 112, first paragraph, written description

Claims 1, 2, 11, 12 and 17 were rejected under 35 U.S.C. § 112, first paragraph, for allegedly lacking written description support. Specifically, the Examiner asserts that the term TNF-gamma-beta encompasses a genus of proteins unsupported by the specification. Applicants respectfully traverse this rejection.

Without acquiescing to the rejection and solely to advance prosecution, the claims have been amended to require that the protein to which the antibody binds is at least 95% identical to SEQ ID NO:20. As explained by the Federal Circuit, "[t]he written description requirement does not require the applicant 'to describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.;" *Union Oil Co. of Cal. v. Atlantic Richfield Co.*, 208 F.3d 989, 997 (Fed. Cir. 2000). Here, one of skill in the art would readily understand what is encompassed by a protein with a sequence at least 95% identical to SEQ ID NO:20, and therefore antibodies that specifically bind and antagonize such proteins. Guidance is provided for making such proteins and antibodies throughout the specification, notably in paragraphs 256 and 298 as well as in Example 34. Therefore, the scope of the claimed invention is well supported in the specification, and Applicants respectfully request that the rejection be withdrawn.

IV. Rejections under 35 U.S.C. § 112, second paragraph

Claims 1, 2, 11, 12 and 17 were rejected under 35 U.S.C. § 112, second paragraph, for allegedly being indefinite. Specifically, the Examiner asserts that the term TNF-gamma-beta is unclear for not identifying the material elements unique to the protein. As discussed previously, without acquiescing to the rejection and solely to advance prosecution, the claims have been amended to recite that the protein to which the antibody binds is at least 95% identical to SEQ ID NO:20. As a person of skill in the art would readily recognize the genus of polypeptides that are at least 95% identical to SEQ ID NO:20, and therefore be able to identify the antibodies that specifically bind them, the claims are definite. Applicants therefore respectfully request that the rejection be withdrawn.

CONCLUSION

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date March 4, 2008

By

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BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF
THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

INTERNATIONAL FORM

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT ISSUED PURSUANT TO RULE 7.3
AND VIABILITY STATEMENT ISSUED PURSUANT TO RULE 10.2

To: (Name and Address of Depositor or Attorney)

Human Genome Sciences, Inc.
Attn: James H. Davis
9410 Key West Avenue
Rockville, MD 20850

Deposited on Behalf of: Human Genome Sciences, Inc.

Identification Reference by Depositor:	**ATCC Designation**
DNA Plasmid HEMCZ56 (647670) (Ref. Docket PF141PP3)	203055

The deposits were accompanied by: ___ a scientific description _ a proposed taxonomic description indicated above. The deposits were received July 9, 1998 by this International Depository Authority and have been accepted.

AT YOUR REQUEST: X We will inform you of requests for the strains for 30 years.

The strains will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the strains, and ATCC is instructed by the United States Patent & Trademark Office or the depositor to release said strains.

If the cultures should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace them with living cultures of the same.

The strains will be maintained for a period of at least 30 years from date of deposit, or five years after the most recent request for a sample, whichever is longer. The United States and many other countries are signatory to the Budapest Treaty.

The viability of the cultures cited above was tested August 5, 1998. On that date, the cultures were viable.

International Depository Authority: American Type Culture Collection, Manassas, VA 20110-2209 USA.

Signature of person having authority to represent ATCC:

Barbara M. Hailey

Barbara M. Hailey, Administrator, Patent Depository

Date: August 18, 1998